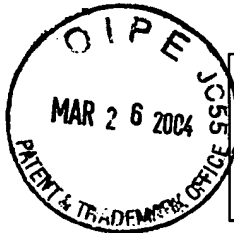


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Dated: 3/26/04

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Anna P. Lucey
(Anna P. Lucey)

Docket No.: ESCL-P01-124
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:

Clarke et al.

Examiner: Not Yet Assigned

Application No.: 10/629933

Confirmation No.: 9050

Filed: July 29, 2003

Art Unit: 1645

For: MULTI-STEP METHOD FOR THE
DIFFERENTIATION OF INSULIN
POSITIVE, GLUCOSE RESPONSIVE
CELLS

INFORMATION DISCLOSURE STATEMENT (IDS)

Commissioner for Patents
P.O. Box 1450
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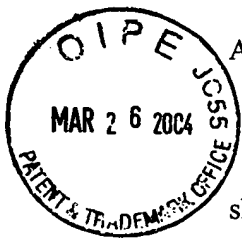
Dear Sir:

Pursuant to 37 CFR 1.56, 1.97 and 1.98, the attention of the Patent and Trademark Office is hereby directed to the references listed on the attached Form PTO/SB/08. It is respectfully requested that the information be expressly considered during the prosecution of this application, and that the references be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

This Information Disclosure Statement was filed before the mailing date of a first Office Action on the merits as far as is known to the undersigned (37 CFR 1.97(b)(3)).

A copy of each foreign patent and non patent reference listed on the attached Form PTO/SB/08 has been included.

While the information and references disclosed in this Information Disclosure Statement may be "material" pursuant to 37 CFR 1.56, it is not intended to constitute an admission that any patent, publication or other information referred to therein is "prior art" for this invention unless specifically designated as such (37 CFR 1.97(h)).



Application No.: 10/629933

Docket No.: ESCL-P01-124

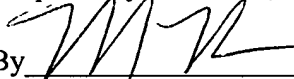
In accordance with 37 CFR 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made or that no other material information as defined in 37 CFR 1.56(a) exists. Applicants further reserve the right to take appropriate action to establish the patentability of the disclosed invention over the listed documents should one or more of the documents be applied against the claims of the present application.

It is submitted that the Information Disclosure Statement is in compliance with 37 CFR 1.98 and the Examiner is respectfully requested to consider the listed references.

The Director is hereby authorized to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 18-1945, under Order No. ESCL-P01-124.

Dated: *March 26, 2004*

Respectfully submitted,

By 

Melissa S. Rones, Ph.D.

Registration No.: 54,408

ROPES & GRAY LLP

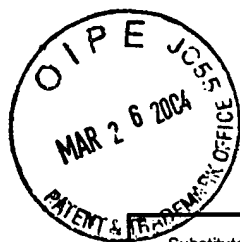
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Attorneys/Agents For Applicant



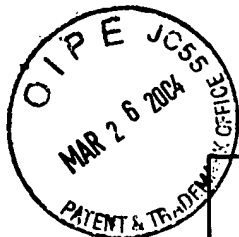
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| | | | | Application Number | 10/629933 |
| | | | | Filing Date | July 29, 2003 |
| | | | | First Named Inventor | Diana Clarke |
| | | | | Art Unit | 1645 |
| | | | | Examiner Name | Not Yet Assigned |
| Sheet | 3 | of | 4 | Attorney Docket Number | ESCL-P01-124 |

| | | | |
|--|----|---|--|
| | BF | Mather, J.P. et al. Activins, Inhibins, and Follistatins: Further Thoughts on a Growing Family of Regulators. P.S.E.B.M. 215, 209-222 (1997). | |
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| | BI | Peck, A.B. et al. Use of In Vitro-Generated, Stem Cell-Derived Islets to Cure Type 1 Diabetes. Ann. N.Y. Acad. Sci. 958, 59-68 (2002). | |
| | BJ | Perry, D. Patients' Voices: The Powerful Sound in the Stem Cell Debate. Science 287, 1423 (25 Feb. 2000). | |
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| | BS | Tourel, C. et al. Persistent Improvement of Type 2 Diabetes in the Goto-Kakizaki Rat Model by Expansion of the Beta-Cell Mass During the Prediabetic Period with Glucagon-Like Peptide-1 or Exendin-4. Diabetes 51, 1443-1452 (May 2002). | |
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| Examiner Signature | Date Considered | |
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| | | | | First Named Inventor | Diana Clarke |
| | | | | Art Unit | 1645 |
| | | | | Examiner Name | Not Yet Assigned |
| | | | | Attorney Docket Number | ESCL-P01-124 |
| Sheet | 1 | of | 4 | | |

| U.S. PATENT DOCUMENTS | | | | | |
|-----------------------|-----------------------|---|--------------------------------|--|---|
| Examiner Initials* | Cite No. ¹ | Document Number Number-Kind Code ² (if known) | Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear |
| | AA | 6,326,201-B1 | 12-04-2001 | Fung et al. | |

| FOREIGN PATENT DOCUMENTS | | | | | | |
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| Examiner Initials* | Cite No. ¹ | Foreign Patent Document Country Code ³ -Number ⁴ -Kind Code ⁵ (if known) | Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear | T ⁶ |
| | AB | WO 95/18856-A1 | 07-13-1995 | Harvard College | | |
| | AC | WO 96/17924-A2 | 06-13-1996 | Johns Hopkins University | | |
| | AD | WO 00/47720-A2 | 08-17-2000 | Ontogeny, Inc. | | |
| | AE | WO 02/12452-A2 | 02-14-2002 | Curis, Inc. | | |

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| NON PATENT LITERATURE DOCUMENTS | | | | |
|---------------------------------|-----------------------|---|--|----------------|
| Examiner Initials ² | Cite No. ¹ | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | | T ² |
| | AF ^{pp} | Abraham, E.J. et al. Insulinotropic Hormone Glucagon-Like Peptide-1 Differentiation of Human Pancreatic Islet-Derived Progenitor Cells into Insulin-Producing Cells. Endocrinol 143(8), 3152-3161 (2002). | | |
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| | AH | Apelqvist, A. et al. Sonic hedgehog directs specialized mesoderm differentiation in the intestine and pancreas. Curr. Biol. 7, 801-804 (1997). | | |
| | AI [†] | Aziz, A. and Anderson, G.H. Exendin-4, a GLP-1 Receptor Agonist, Modulates the Effect of Macronutrients on Food Intake by Rats. J. Nutr. 132, 990-995 (2002). | | |
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| | AN [‡] | Doyle, M.E. and Egan, J.M. Glucagon-Like Peptide-1. Recent Prog. Horm. Res. 56, 377-399 (2001). | | |

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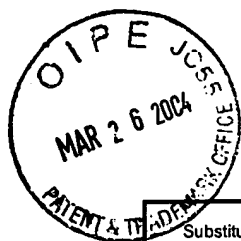
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| | | | | Filing Date | July 29, 2003 |
| | | | | First Named Inventor | Diana Clarke |
| | | | | Art Unit | 1645 |
| | | | | Examiner Name | Not Yet Assigned |
| Sheet | 2 | of | 4 | Attorney Docket Number | ESCL-P01-124 |

| | |
|----|---|
| AO | Edlund, H. Transcribing Pancreas. Diabetes 47, 1817-1823 (Dec. 1998). |
| AP | Edlund, H. Developmental Biology of the Pancreas. Diabetes 50 (Supp.1), S5-S9 (Feb. 2001). |
| AQ | Egan, J.M. et al. The Insulinotropic Effect of Acute Exendin-4 Administered to Humans: Comparison of Nondiabetic State to Type 2 Diabetes. J. Clin. Endocrinol. Metab. 87(3), 1282-1290 (2002). |
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| BB | Lampeter, E.F. et al. Regeneration of Beta-cells in Response to Islet Inflammation. Exp. Clin. Endocrinol. 103, 74-78 (1995). |
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| BE | Maldonado, T.S. et al. Ontogeny of Activin B and Follistatin in Developing Embryonic Mouse Pancreas: Implications for Lineage Selection. J. Gastrointest. Surg. 4, 269-275 (2000). |

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| | | | | Art Unit | 1645 |
| | | | | Examiner Name | Not Yet Assigned |
| | | | | Attorney Docket Number | ESCL-P01-124 |
| Sheet | 4 | of | 4 | | |

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| | BW | Welt, C. et al. Activins, Inhibins, and Follistatins: From Endocrinology to Signaling. A Paradigm for the New Millennium. Exp. Biol. Med. 227, 724-752 (2002). | |
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